## REMARKS

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 25, 2005. Claims 1, 75, 76, 81, 83 and 84 have been amended, and claims 87-93 have been added. Claims 1 and 59-93 are pending. Support for the amendments can be found in the specification, claims, and drawings as originally filed. No new matter has been added. Reconsideration and reexamination are respectfully requested.

**Allowable Subject Matter**

Applicants thank the Examiner for indicating that claims 66, 67, 72-74, 78 and 85 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. New claims 87-93 correspond to claims 66, 67, 72-74, 78 and 85, respectively. The main claims are rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants submit that new claims 87-93 are thus allowable.

**Rejections under 35 U.S.C. § 102**

Claims 1, 59-62, 68-71, 75, 76 and 79-83 are rejected as being anticipated by Heilman et al. (US 4,030,509). Applicants respectfully traverse the rejection.

Independent claim 1, as amended, recites an implantable lead electrode assembly having an electrode, a backing layer and a fin, wherein the backing layer has top and bottom surfaces and the bottom surface contacts the top of the electrode, and the backing layer forms the fin which projects from the top surface of the backing layer. Heilman et al. teach a device in which an insulating material 110 covers the back surface of a conductive mesh 102 and wraps around the edge of the mesh 112. Applicants submit that the edge 112 of the insulating material 110 is not a "fin" as claimed in the context of the instant application. Additionally, the edge 112 of the insulating material 110 of Heilman et al. does not project from the top surface, i.e., the opposite side from where the electrode is attached. At best, Heilman et al. teach edge 112 projecting from the bottom surface of the insulating material 110. Heilman et al. do not teach or suggest anything projecting from the top surface of a backing layer positioned over the top of an electrode, as is now recited in claim 1. Additionally, there is no motivation or guidance for one

of ordinary skill in the art to modify the device of Heilman et al. to achieve an implantable lead electrode assembly as recited in claim 1. Heilman et al. thus do not teach or suggest each and every element of independent claim 1, or the claims dependent thereon.

Independent claim 75, as amended, recites an implantable lead electrode assembly having an electrode and a backing layer with an integral fin, wherein a base portion of the backing layer and the fin are substantially planar and the fin extends laterally from and in the same plane as the base portion of the backing layer, with the fin extending beyond an outside edge of the base portion of the backing layer. Heilman et al. do not teach or suggest such a device. Heilman et al. teach an insulating material 110 that wraps around an edge 112 of a conductive wire mesh 102. FIG. 6 of Heilman et al. shows edge 112 extending away from the main portion of the insulating material 110 in order to curl around the edge of the mesh 102. Additionally, Heilman et al. provide no motivation, suggestion or guidance for one of ordinary skill in the art to modify their device to include the features set forth in claim 75. Heilman et al. thus fail to teach or suggest the elements of independent claim 75, and the claims dependent thereon.

Independent claim 81, as amended, recites an implantable lead electrode assembly having an electrode, a backing layer, and a flexible fin configured such that with the application of pressure against the fin, the fin moves between an extended position in which the fin has a first appendage height to a folded position in which the appendage height of the fin is reduced, the fin moving back to the extended position when the pressure is released. Heilman et al. do not teach such a fin. Heilman et al. teach a flexible insulating material 110 surrounding the conductive wire mesh 102 at edges 112 to minimize the possibility of tissue damage. See column 8, lines 26-32. While the insulating material 110 of Heilman et al. may be somewhat flexible, the edges 112 do not move between an extended position and a folded position and back to an extended position with the application and removal of pressure. In order for the edges 112 to surround and retain the wire mesh 102, the edges 112 must be permanently folded over the wire mesh. Edges 112 of Heilman et al. thus do not read on the "fin" as recited in claim 81. Additionally, there is no motivation for one of ordinary skill in the art to modify the device of Heilman et al. to have such a feature because doing so would appear to release the wire mesh 102, which would destroy the usefulness of the device. Heilman et al. thus fail to teach or suggest each and every element of independent claim 81 and the claims dependent thereon.

Regarding claim 83, the Examiner asserts that one can bend tip 116 of Heilman et al. so that it lies parallel to the electrode. Applicants submit that there is no teaching or suggestion in Heilman et al. that would indicate to one of ordinary skill in the art that the tip 116 could be bent parallel to the electrode. Heilman et al. teach tip 116 as being rigid and adapted to pierce the epicardium. See column 8, lines 37 and 47-48. Applicants submit that one of ordinary skill in the art, upon reading Heilman et al.'s description of the rigid tip 116 that is designed to pierce the epicardium, would not interpret tip 116 as being movable or bendable to a position parallel to the electrode. Additionally, because Heilman et al. teach the tip 116 as being adapted to pierce the epicardium for pacing, there is no reason one would wish to bend the tip parallel to the electrode, because doing such would destroy the functionality of the tip. Heilman et al. thus specifically teaches away from the fin as described in claim 83.

For at least the reasons set forth above, Heilman et al. fail to teach or suggest each and every element of independent claims 1, 75 and 81, and the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

Claims 84 and 86 are rejected as being anticipated by Rockland et al. (US 4,010,758). Applicants respectfully traverse the rejection. Claim 84, as amended, recites a lead electrode assembly having an electrode, a backing layer, and an appendage extending from the first face of the electrode through the backing layer, and the appendage does not extend beyond the second face of the electrode. Rockland et al. teach an electrode assembly in which a helical electrode 18 extends through and beyond both the first and second faces of plate-like electrode 21, as shown in FIG. 2b. Rockland et al. thus fail to teach the elements of amended claim 84. Additionally, there is no motivation or suggestion for one of ordinary skill in the art to modify the electrode assembly of Rockland et al. such that helical electrode 18 did not extend beyond the second face of plate-like electrode 21 because doing so would remove the helical screw portion of the electrode and thus destroy the functionality of electrode 18. Rockland et al. teach screwing electrode 18 into the endocardium of the heart in order to position the electrode assembly. Electrode 18 thus must extend beyond the second face of electrode 21 in order for the assembly to function. Rockland et al. do not teach or suggest each and every element of independent claim 84 and the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. § 103**

Claims 63-65 and 77 are rejected as being unpatentable over Heilman et al. Applicants respectfully traverse the rejection. Claims 63-65 are dependent from claim 1, which is allowable over Heilman et al. for the reasons set forth above. Claim 77 is dependent from claim 75, which is also allowable over Heilman et al. for the reasons set forth above.

Additionally, with regard to claims 64, 65, and 77, the Examiner takes Official Notice that it is old and well-known in the medical electrode arts to utilize covers (i.e., packages) for implantable lead assemblies in order to maintain a sterile environment prior to implant and protect the delicate lead assembly. The Examiner also states that because Applicants have not invoked the 6th paragraph of 112 by reciting "means plus function" language, the Examiner is not restricted to find covers that are the same or equivalent to those set forth in the present specification, and that any element that can act as a cover would be of relevance to the claim. Applicants respectfully disagree.

MPEP 2111.01 states:

> It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. Ferguson Beauregard/Logic Controls v. Mega Systems, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003).

Emphasis added. Applicants submit that the use of "cover" in the written description does not include packaging, and that one of ordinary skill in the art, upon reading the instant specification, would not interpret the claimed "cover" as the packaging used to maintain sterility and to transport the device. Additionally, the claims recite an implantable lead electrode assembly comprising a cover. The cover is thus a part of the implantable electrode assembly, and as such, in use, would be implanted with the rest of the assembly. Furthermore, the Examiner has admitted that elements that can act as a cover are of relevance to the claim. However, in view of the teachings of the specification regarding the claimed cover, packaging materials would not act as a cover as described and claimed. Packaging materials are thus not of relevance to the claim.

In light of the above remarks, withdrawal of the rejections, reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By their Attorney,

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